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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,704	09/21/2006	Jun Hirabayashi	20846/0205032-US0	9747

7278 7590 02/03/2010
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EXAMINER

SKOWRONEK, KARLHEINZ R

ART UNIT	PAPER NUMBER
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1631

MAIL DATE	DELIVERY MODE
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02/03/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/596,704	Applicant(s) HIRABAYASHI ET AL.	
	Examiner KARLHEINZ R. SKOWRONEK	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 1-5 and 12-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 12-14 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/26/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Newly submitted claims 12-14 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Originally filed claims 1-5 were directed to the analysis of saccharides employing a FAC (frontal affinity Chromatography) apparatus. Originally filed claims 6-11 were directed to the analysis of saccharides employing the immobilization of saccharide binding proteins that does not require a FAC apparatus. Hirabayashi et al. (IDS cite CD, submitted 2 February 2007) demonstrates the FAC apparatus relies on the immobilization of saccharide binding proteins to measure the interaction between saccharides and proteins to analyze saccharide structure. Thus, the corresponding technical feature, i.e. the immobilization of saccharide binding proteins to measure the interaction between protein and saccharide for the analysis of saccharide structures, was known in the art and is not a special technical feature. New claims 12 and 13 are directed to a process of saccharide analysis employing a FAC apparatus as in non-elected claims 1-5. New claim 14 is directed to an embodiment of claim 9 in which a computer is configured to calculate an elution volume from a column in a determination of saccharide structure. Originally filed claim 9 does not require the use of columns or elution to measure interaction. Thus, claim 14, which requires the use of columns and elution or washing, is not directed to the elected invention.

Accordingly, claims 12-14 are withdrawn from consideration as being directed to a non-elected invention.

Claim Status

Claims 1-14 are pending.

Claims 12-14 are new.

Claims 1-5 and 12-14 are withdrawn as being directed to a non-elected invention.

Claims 6-11 have been examined.

Claims 6-11 are rejected.

Priority

This application was filed on 21 September 2006 and is the 35 USC 371 National Stage Application of PCT/JP04/09600, filed on 30 June 2004 and claims priority to Japanese Application No. 2003-430615, filed on 25 December 2003.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 26 October 2009 was filed after the mailing date of the First Action on the Merits on 18 August 2009. The submission complies with the provisions of 37 CFR 1.97(c). Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

Response to Arguments

The rejection of claims 9-11 as indefinite under 35 USC 112, Second paragraph and lacking written description under 35 USC 112, First paragraph with respect to limitations interpreted as invoking 35 USC 112, Sixth paragraph is withdrawn in view of the amendments to the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The following rejection is reiterated from the previous action.

Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang (WO 02/083918) in view of Nilsson (Analytical Chemistry, Volume 75, Issue 15,

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p.348-353, 01 August 2003) and in view of Joos et al. (Current Opinion in Chemical Biology, 2001, Vol. 6, p.76-80).

Claim 6 is directed to a method of analyzing oligosaccharides in which a fluorescently labeled oligosaccharide sample contacts a solid support comprising a plurality of proteins and detecting the pattern of protein-oligosaccharide binding without washing. In the embodiment of claim 7, the excitation light is an evanescent wave. In the embodiment of claim 8, the protein is a lectin.

Wang shows method of detecting the binding of an agent to a microarray (p. 28). Wang shows, as in the embodiment of claim 8, lectins, or antibodies are immobilized on the microarray (p. 28). Wang defines agents to be glycomers or oligosaccharides (p. 22 and p. 23). Wang shows the determination of binding is made by detecting fluorescence (p. 29).

Wang et al. does not explicitly show determining a pattern of oligosaccharide binding to lectin to analyze structure or detecting without washing.

Nilsson provides a discussion of lectins and their binding of oligosaccharides. Nilsson shows lectins are proteins that recognize and bind to specific carbohydrate structural epitopes (p. 349, col. 2). Nilsson shows that lectins recognize different sugar structures, make lectins invaluable biochemical tools (p.350, col. 1). Nilsson shows using microarray techniques binding partners can be made by either linking the protein or the carbohydrate to a solid surface (p. 351, col. 1). Nilsson shows that the pattern of lectin binding to oligosaccharides can be determined using microarrays (p. 351, col. 1). Thus, the structural organization of the saccharide constituents is determined.

Joos et al. shows that the sensitivity of protein arrays can be increased by excitation of fluorophores with evanescent waves (p. 78, col. 1). The use of evanescent waves also allows performing microarray binding detection without washing steps (p. 78, col. 1). Joos et al. shows that (p. 78, col. 1).

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Wang for the detection of oligo saccharide agents using lectins immobilized on a substrate to analyze oligosaccharide structure as suggested by Nilsson because Nilsson shows the ability of lectins to recognize different sugar structures makes lectins in valuable biochemical tools. It would have been further obvious to one of ordinary skill in the art at the time of invention to modify the method of Wang for the detection of oligo saccharide agents using lectins immobilized on a substrate to analyze oligosaccharide structure as suggested by Nilsson with detection using evanescent waves of Joos et al. because Joos et al. shows evanescent waves have the advantage of providing signals that are a hundred times higher than conventional excitation.

Response to Arguments

Applicant's arguments filed 18 November 2009 have been fully considered but they are not persuasive. Applicant argues lectin/sugar binding specificity was unknown to those of ordinary skill in the art at the time of invention. The argument is not persuasive. Nilsson shows that lectins were well known at the time of invention to possess distinct oligosaccharide binding capabilities. For example, Nilsson shows the use of lectins as biochemical tools to elucidate the chemical structure of the ABH histo-

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blood group antigens, the system that is based on the structural differences in terminal saccharides in human glycolipids and glycoproteins in the 1950's (p. 349, col. 2-p. 350, col. 1). Applicant argues the one would not have been motivated to immobilize proteins that interact with sugar chains to analyze sugar chains. The argument is not persuasive. Nilsson shows that during 2002 three reports were published that detailed large scale methods to study protein carbohydrate interaction by microarray techniques which are based on the finding the binding partners can be made by either linking the protein or the carbohydrate to a solid substrate (p. 350, col. 2-p. 351, col. 1). Applicant argues that that one would have not been motivated by Nilsson to modify the method of Wang to use lectins. The argument is not persuasive. Nilsson shows that at least three independent research groups successfully developed methodologies to probe protein-saccharide interactions. Applicant cites p. 350, column 2 of Nilsson that states, "The area presents special analytical challenges because of the weak nature of the biomolecular interactions and the solubility differences between carbohydrates, which are extremely hydrophilic, and proteins, which have a wide range of hydrophobicities". However, Nilsson qualifies the previous statement at p. 350, col. 2, para. 3, last three lines, "The low affinity of lectins for carbohydrates is, to some extent, compensated for by their multivalency, which increases the avidity of the binding." With respect to applicants argument that a person at the time of invention would not have able to distinguish the structures of sugar chains without the detailed explanation found in applicants specification is not persuasive. As indicated above Nilsson shows that lectins

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and saccharide binding proteins have been used successfully since the 1950's to elucidate saccharide structures. The rejection is maintained.

The following rejection is reiterated from the previous action.

Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang in view of Nilsson in view of Joos et al. as applied to claims 6-8 above, and further in view of and Shalon et al. (Genome Res., Vol. 6, p. 639-645, 1996) in view of Pawlak et al. (Proteomics 2002, 2, 383-393).

Claim 9 is directed to a system comprising a storage means; a detection means; a calculating means, and a displaying means that implements a method of analyzing sugar chains.

Wang in view of Nilsson in view of Joos et al. as applied to claims 6-8 above shows a method of analyzing sugar chains using evanescent waves.

Wang in view of Nilsson in view of Joos et al. does not explicitly show a system

Shalon et al. shows a microarray system comprising a storage means; a detection means; a calculating means, and a displaying means (p. 644, col. 2).

Pawlak et al. shows a microarray system adapted with a specialized detection means to detect signals from microarray substrates that rely on evanescent waves (p. 385, col. 1). Pawlak et al. shows that the differences between the evanescent wave and conventional excitation, such as that performed in Shalon et al., is approximately an 80-fold increase in signal to noise (figure 1). Pawlak et al. shows the evanescent wave excitation allows one to omit washing steps during microarray hybridization that is

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especially beneficial for weak affinity reactions as a dissociation of weak complexes during washing can be avoided (p393, col. 1).

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Wang in view of Nilsson in view of Joos et al. as applied to claims 6-8 above to perform the method with the system of Shalon et al. because all the claimed elements were known, in the prior art, and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art at the time of the invention. It would have been further obvious to modify the detection means of Shalon et al. with the detection means of Pawlak et al. because Pawlak et al. shows the evanescent wave excitation allows one to omit washing steps during micro array hybridization which is especially beneficial for weak affinity reactions as a dissociation of weak complexes during washing can be avoided.

Response to Arguments

Applicant's arguments filed 18 November 2009 have been fully considered but they are not persuasive. Applicant argues that Shalon et al. and Pawlak do not cure the deficiencies of Wang et al., Nilsson, and Joos et al. The argument is not persuasive because Wang et al., Nilsson, and Joos et al. are not deficient for the reasons provided above. The rejection is maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The following rejection is reiterated from the previous action.

Claims 6-8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 11, and 12 of copending Application No. 10/596692. Although the conflicting claims are not identical, they are not patentably distinct from each other. The method as in claim 6 of the instant application is directed to a method in which a fluorescent oligosaccharide is contacted with a substrate comprising immobilized protein and measuring the interaction. Similarly, in claim 1 of copending Application No. 10/596,692, a method is claimed in which a fluorescent oligosaccharide is contacted with a substrate comprising immobilized protein and measuring the interaction.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed 18 November 2009 have been fully considered but they are not persuasive. Applicant argues that a terminal disclaimer will be filed upon indication of allowable subject. The provisional rejection is maintained.

The following rejection is reiterated from the previous action.

Claims 9-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 11/917,921. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 9-11 of the instant application are directed to an apparatus or system comprising a storage means, detection means, calculation means, and a display means in which evanescent waves are used to excite fluorophores and lectins are immobilized on a substrate. Similarly, claims 1-9 of copending Application No. 11/917,921 are also directed to an apparatus comprising storage means, a measuring or detecting means, and a calculation means. Although claims 1-9 of copending Application No. 11/917,921 does not show a display means, it would be obvious to one of ordinary skill in the art to modify the apparatus of copending Application No. 11/917,921 to include a display means. Such a modification would advantageously provide results of the apparatus function to the user.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed 18 November 2009 have been fully considered but they are not persuasive. Applicant argues that a terminal disclaimer will be filed upon indication of allowable subject. The provisional rejection is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KARLHEINZ R. SKOWRONEK whose telephone number is (571)272-9047. The examiner can normally be reached on 8:00am-5:00pm Monday-Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KARLHEINZ R SKOWRONEK/
Examiner, Art Unit 1631

2 February 2010